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Amendments to the Specification

Please replace paragraph [0012] with the following rewritten paragraph:

A1

– This paradox has significant clinical implications. Frequently during resuscitation, certain blood tests are performed which measure[[s]] the amount of oxygen and carbon dioxide in the blood. When such examinations reveal decreased oxygen levels or, more importantly, elevated amounts of carbon dioxide in the blood, the individual ventilating is usually prompted to ~~provide~~ increase their efforts. The natural response would be to increase the ventilatory rate, however, higher ventilatory rates have been associated with increased operator hand fatigue and inattentiveness. Consequently, tidal volumes have been observed to decrease as ventilatory rates increase. Therefore, despite increased ventilatory rate (and operator impression they are providing improved ventilation), overall ventilatory effectiveness may actually decrease, because as tidal volume decreases anatomic deadspace represents increasing proportions of each breath, which can provide a greater negative affect on alveolar ventilation than the positive effect of a higher rate. –.

Please replace paragraph [0017] with the following rewritten paragraph:

A2

– Other measures can be employed to palliate these deficiencies of the prior art. A more definitive form of airway control involves placement of a tube (called an endotracheal tube) directly into the patient's trachea, thus isolating the airway from the ~~gastrointestional~~ gastrointestinal tract. After intubation, the face mask can be detached and the manual resuscitator directly connected to a port on the endotracheal tube. This obviates the need for active airway maintenance, provides definitive airway protection, and allows a single rescuer to use two hands to ventilate the patient. –.

Please replace paragraph [0021] with the following rewritten paragraph:

A3

– However, employing a two-handed technique in the intubated patient, while preventing the harmful effects of hypoventilation and hypercarbia, are associated with the aforementioned risks due to generation of excessive tidal volumes, airway

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A7 pressures, and flow rates. ~~other significant risks.~~ The potential for lung injury is more pronounced when the patient is intubated since, under these circumstances, the endotracheal tube provides a sealed, direct connection between the manual resuscitator and the patient's lungs. Accordingly, excessive or over-aggressive ventilatory techniques, encouraged in-part by the intense environment of frantic resuscitation efforts, have been documented to cause traumatic injury to the lungs, particularly in pediatric and elderly patients. --.

Please replace paragraph [0031] with the following rewritten paragraph:

A4 -- ~~(d)~~ (c) to provide a ramped flow rate when used on adult patients, whereby low flow rates are provided at the beginning of a breath and slowly increase toward end-inspiration, which improves distribution of gas in the lung; --.

Please replace paragraph [0032] with the following rewritten paragraph:

A5 -- ~~(e)~~ (d) to consistently provide full, effective, and uniform tidal volumes without regard to technique, thus allowing a physician to prescribe a specific and predictable degree of ventilatory support tailored to the patient's specific physical attributes and underlying illness; --.

Please replace paragraph [0033] with the following rewritten paragraph:

-- ~~(f)~~ (e) to provide safeguards to prevent patient harm caused by the delivery of excessive tidal volumes, airway pressures, and flow rates; --.

Please replace paragraph [0034] with the following rewritten paragraph:

-- ~~(g)~~ (f) to enable assertive delivery of large tidal volumes without jeopardizing patient safety, thus providing safer, more effective ventilation; --.

Please replace paragraph [0035] with the following rewritten paragraph:

-- ~~(h)~~ (g) to provide consistent volumes with each breath, increasing the uniformity of airway pressures sensed by the operator and accordingly the ability to

detect progressively increasing airway resistance, which also increases the clinical applicability of certain monitoring tests; --.

A5 cont'd

Please replace paragraph [0036] with the following rewritten paragraph:

-- ~~(i)~~ (h) to provide an ability to prescribe a specific maximum airway pressure to which the patient will be exposed; --.

Please replace paragraph [0037] with the following rewritten paragraph:

-- ~~(k)~~ (i) to enable adequate tidal volumes to be administered to unintubated patients at low airway pressures, thus decreasing the incidence and significance of gastric insufflation and risk to the unprotected airway; --.

Please replace paragraph [0038] with the following rewritten paragraph:

-- ~~(l)~~ (j) to provide a new ability to detect progressively increasing airway pressure by combining the use of both volume and pressure safeguard mechanisms; and --.

Please replace paragraph [0039] with the following rewritten paragraph:

-- ~~(m)~~ (k) to provide an improved ability to detect underlying intrathoracic injuries and/or a displaced endotracheal tube through detection of decreasing pulmonary compliance[[;]]. --.

Please replace paragraph [0042] with the following rewritten paragraph:

A6

-- Figs 2a-d show[[s]] components of an example embodiment of a volume restrictor. Fig 2a shows a cone-shaped inflow obturator which contains a number of inflow fluid conduits to enable flow of fluid through the resuscitator. Fig 2b shows a donut-shaped inflow obturator spacer with an opening or lumen in the center to permit fluid flow. Fig 2c shows a combination cone-shaped inflow obturator together with the inflow obturator spacer, the two of which may be permanently joined into a single component. Fig 2d shows an outflow obturator, which, other than orientation, is identical to the inflow obturator. --.

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Please replace paragraph [0043] with the following rewritten paragraph:

-- Figs 3a-c show[[s]] additional components of another example embodiment of a volume restrictor. Fig 3a shows a disk-shaped placement selector, which contains numerous fluid conduits to permit fluid flow. Fig 3b shows a ring-shaped inflow selector spacer, and Fig 3c shows these two components assembled together with the addition of a placement cam, all three of which form a single assembly. --.

Please replace paragraph [0044] with the following rewritten paragraph:

-- Figs 4a-c show[[s]] sequential assembly of the invention, including all components of the example embodiment of the volume restrictor. Fig 4a demonstrates how the inflow and outflow obturators are positioned onto the placement cam. Fig 4b shows complete assembly of the volume restrictor. Fig 4c shows the combined assembly of the volume restrictor and the example embodiment of the bellows, with the addition of a fluid chamber skin. --.

Please replace paragraph [0046] with the following rewritten paragraph:

-- Fig 6b shows the invention whereby the volume restrictor has been adjusted to provide delivery of a reduced volume[[s]]. Fig 6a provides a comparison view of the volume restrictor in the position to provide full, unimpeded volume delivery. --.

Please replace paragraph [0049] with the following rewritten paragraph:

-- Figs 9a-b show[[s]] a propeller-shaped stopper, which when placed adjacent to the pressure restrictor housing, provides for selective fluid flow through the housing based on the rotational position of the stopper. --.

Please replace paragraph [0050] with the following rewritten paragraph:

-- Fig 10a shows the combined outer housing and stopper of the example embodiment of a pressure restrictor, whereby the stopper is oriented in a position to permit fluid flow through the housing via the housing fluid conduits, which are

unobstructed. In Fig 10b, the stopper is depicted in a rotational orientation whereby the stopper obstructs the housing fluid conduits, thus interrupting fluid flow through the pressure restrictor. Figs 10a-b also show[[s]] an example embodiment of a controller of the pressure restrictor which employs a compressible spring which surrounds the outer housing of the pressure restrictor. –.

A7 cont

Please replace paragraph [0050] 51 with the following rewritten paragraph:

– Figs 11a-b demonstrate[[s]] the same variable positions of the stopper depicted in Figs 10a-b. However, in Figs 11a-b the pressure restrictor controller has been adjusted to a position which provides greater compression of the controller spring, changing the operational dynamics of the pressure-controller. –.

Please replace paragraph [0052] with the following rewritten paragraph:

A8

– In Fig 1 an example embodiment of a bellows is depicted. A plurity of rectangular structural members 10 can be seen to be coupled together along their long axis, whereby the combination of all the attached structural members can collectively be regarded as a bellows structure 12. The bellows structure 12 is preferably formed into a cylindrical shape by wrapping the bellows structure 12 into a circular shape along the bellows short axis. This shape enables identification of an interior surface 16 of the bellows structure and an exterior surface 14 of the bellows structure 12. The three-dimensional space contained by the bellows structure interior surface 16 can constitute a fluid chamber 18 of a particular definitive volume. In this example embodiment, the coupling of the bellows structural members 10 is provided along those edges which meet along the bellows structure interior surface 16. Accordingly, adjacent structural members 10 may flex in a direction toward the interior of the bellows structure 12, providing for a concave curvature of the bellows structure interior surface 16 and a convex curvature of the bellows structure exterior surface 14. Conversely, this coupling of adjacent structural members 10 does not provide for flexing in a direction outward from the bellows structure 12, which would require a concave curvature of the bellows structure exterior surface 14, because this would necessarily have to result from a

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convex curvature along the bellows structure interior surface 16, which is not possible since this would require separation of coupled edges of adjacent structural members 10. Accordingly, in ~~Fib~~ Fig 1b the bellows structure 12 can be seen to be in a partially inflated condition, whereby the fluid chamber 18 is of a diminished volume compared to the volume of that depicted in Fig 1a. Since outward flexing of the adjacent structural members 10 is prevented by the aforementioned coupling, an application of a compressing force on the bellows structure exterior surface 14 will result in a transition of the bellows structure 12 from the fully inflated condition in Fig 1a to the partially inflated condition depicted in ~~Fib~~ Fig 1b. Sustained application of such a force will eventually result in transition of the bellows structure to the end-point condition depicted in Fig 1c, whereby the bellows structure 12 is flattened into an oblong shape in the fully deflated condition. In this condition the volume contained by the fluid chamber 18 approaches zero. Transition from the deflated condition depicted in Fig 1c back to the inflated condition shown in Fig 1a can be provided through a variety of means, including inclusion of an elastic skin lining the bellows structure interior surface 16 and/or the exterior surface 14, or through forced inflation by a fluid under pressure. –.

Please replace paragraph [0053] with the following rewritten paragraph:

– Fig 2 depicts three components associated with an example embodiment of a volume restrictor designed to be used in conjunction with a bellows in a resuscitator. In Fig 2a a substantially cone-shaped inflow obturator 20 can be seen, having a number of inflow obturator fluid conduits 21 which can be seen to traverse through the cone in a direction perpendicular to the base and parallel to the vertical axis of the cone. These inflow obturator fluid conduits 21 can further be seen to be collectively arranged around the center of the cone in a circular fashion, leaving the outer circumference of the cone free of voids. In the actual center of the inflow obturator 20 is a threaded inflow obturator center bore 20a, which traverses through the inflow obturator 20 in a direction parallel to the inflow obturator fluid conduits 21. –.

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Please replace paragraph [0056] with the following rewritten paragraph:

– Fig 3a shows a disk-shaped placement selector 30 having a number of placement selector fluid conduits 31, which traverse through the placement selector 30 in a direction perpendicular to the flat bases of the placement selector 30. Additionally, the placement selector fluid conduits 31 are arranged in a circular fashion around the center of the placement selector 30, leaving the outer circumference of the placement selector 30 free of voids. In the actual center of the placement selector 30 is a placement selector central bore 30a which traverses through the placement selector 30 in a direction parallel to the placement selector fluid conduits 31. The overall circular diameter and circumference of the placement selector 30 is preferably identical to the diameter and circumference of both the inflow obturator 20 and inflow obturator spacer 24 depicted in Figs 2a-c. –.

Please replace paragraph [0057] with the following rewritten paragraph:

– Fig 3b shows a ring-shaped inflow selector spacer 32 having an inflow selector spacer lumen 33. The outer diameter of the inflow selector spacer 32 is preferably related to the diameter of the inflow obturator spacer lumen 25 shown in Figs 2b-c, whereby the outer diameter of the inflow selector spacer 32 is slightly less than the diameter of the inflow obturator spacer lumen 25, so that the inflow selector spacer 32 may freely rotate or slide to and fro inward or outward within the inflow obturator spacer lumen 25. The diameter of the inflow selector spacer lumen 33 is preferably related to the placement selector fluid conduits 31 and the inflow obturator fluid conduits 21 depicted in Figs 2a-c, whereby the diameter of the inflow selector spacer lumen 33 is sufficiently large enough to encircle the collective arrangements of both the placement selector fluid conduits 31 and inflow obturator fluid conduits 21. The height of the inflow selector spacer 32 is preferably related to the height of the inflow obturator spacer 24 depicted in Figs 2b-c, whereby the height of the inflow selector spacer 32 is slightly greater than the height of the inflow obturator spacer 24. –.

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A9 cont'd

Please replace paragraph [0058] with the following rewritten paragraph:

– Fig 3c depicts the combination of the placement selector 30 and inflow selector spacer 32, whereby one of the two flat bases of the inflow selector spacer 32 is attached to one of the two flat bases of the placement selector 30, wherein the respective cross-sectional center points of the two components are superimposed ~~alone~~ along the same two-dimensional plane, thus allowing the combination of the placement selector fluid conduits 31 and the inflow selector spacer lumen 33 to form a straight, continuous fluid passageway which traverses both the placement selector 30 and inflow selector spacer 33. –.

Please replace paragraph [0059] with the following rewritten paragraph:

– Also depicted in Fig 3c is a shaft-shaped placement cam 34. The length of the placement cam 34 is preferably related to both the length of the bellows structural members 10 (shown in Figs 1a-c), the height of the inflow obturator 20 and outflow obturator 22 (shown in Figs 2a-d), the height of the inflow selector spacer 32, and the height of placement selector 30, wherein the length of the placement cam 34 is equal to the cumulative distance represented by the height of the placement selector 30, the height of the inflow selector spacer 32, the height of the inflow obturator 20, the length of the bellows structural members 10, and the height of the outflow obturator 22. The diameter of the placement cam 34 is slightly less than the diameters of the placement selector center bore 30a, the inflow obturator center bore 20a, and the outflow obturator center bore 22a. Additionally, the outer surface of the placement cam 34 is threaded to mate with the threads of the inflow obturator center bore 20a. In Fig 3c the placement cam can be seen to fit inside the combined placement selector center bore 30a and inflow selector spacer lumen 33, wherein one end of the placement cam 34 is mounted within the placement selector center bore 30a and flush with the flat surface of the placement selector 30 which is opposite that which is in contact with the inflow selector spacer 32. In this position it can be seen the long axis of the placement cam 34 is parallel to the axis of the inflow spacer lumen 33 and placement selector fluid conduits 31. –.

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Please replace paragraph [0062] with the following rewritten paragraph:

A10

-- Accordingly, as previously described and in accordance with Figs 1a-c, application of a compressing force onto the bellows structure <u>12</u> will transition the bellows from the inflated condition depicted in Figs 1a and 5a to the deflated condition depicted in Figs 1c and 5b, which causes a decrease in volume of the fluid chamber 18 contained by the skin 99 and bellows structure interior surface 16. Due to the aforementioned unidirectional fluid flow provided for by the inflow one-way valve <u>77</u>, fluid contained in the fluid chamber 18 in the inflated condition of the invention (as shown in Figs 1a and 5a) will be ejected from the fluid chamber 18, through the outflow obturator fluid conduits 23 and outflow one-way valve 88 as the volume of the fluid chamber 18 is reduced to the minimum associated with the deflated condition (as shown in Figs 1c and 5b). Particularly note that the positioning of the inflow obturator 20 and outflow obturator 22 along placement cam 34 does not interfere or impede the range of travel of the bellows as it transitions from the inflated condition (as shown in Figs 1a and 5a) to the deflated condition (as shown in Figs 1c and 5b). In the opposite fashion, as the volume of the fluid chamber 18 re-expands into the inflated condition, fluid will flow antegrade into the fluid chamber 18 from the inflow obturator fluid conduits 21 from the direction of the inflow one-way valve <u>77</u>. Accordingly, repetitive operation of the bellows results in a fluid-pumping action which provides for operation of the invention.

Please replace paragraph [0065] with the following rewritten paragraph:

A11

-- In Fig 8a components of an example embodiment of a pressure restrictor is shown, comprising a ring-shaped or short-cylindrical outer housing 40. Contained within the interior of the outer housing 40 ~~is~~ are two disk-shaped stopper housings 41 which contain[[s]] numerous housing fluid conduits 42 which permit fluid flow through the pressure restrictor. Encircling the outside surface of the outer housing 40 is a tube-shaped controller channel 44, which at one point empties into a pressure channel 45. Within the controller channel an open-point stop 64 and closed-point stop 65 can be

seen as small projections which partially obstruct the lumen of the controller channel 44.

Please replace paragraph [0067] with the following rewritten paragraph:

– In Figs 9a-b a propeller-shaped stopper 50 is depicted. The number of blades of the stopper 50 is identical to the number of stopper housing fluid conduits 42 (shown in Figs 8a-b), and are further related in shape to the shape of the housing fluid conduits 42, wherein the blades of the stopper 50 are shaped to provide variable coverage over the housing fluid conduits 42. The overall diameter of the stopper 50 is related to the diameter of the stopper notch 43 of the outer housing 40 (both shown in Figs 8a-b), wherein the diameter of the stopper 50 is slightly less than the diameter of the stopper notch 43, whereby the stopper 50 may freely rotate within the stopper notch 43. The thickness of the stopper 50 is also related to the thickness of the stopper notch 43, wherein the thickness of the stopper 50 is slightly less than the thickness of the stopper notch 43, whereby the stopper 50 is contained within the stopper notch 43 and may freely rotate within the stopper notch 43 without substantial to and fro play. Attached to the outer edge of one of the stopper blades is a pressure header spar 51, which supports a pressure header 52. The shape and dimensions of the pressure header 52 is related to the internal shape and dimensions of the controller channel 44, whereby the shape and dimensions of the pressure header 52 allows movement within the controller channel 44 while also forming a substantially airtight seal between the outer edge of the pressure header 52 and the internal wall of the controller channel 44. Attached to an outer edge of one of the stopper blades adjacent to that which is attached to the pressure header spar 51 is a controller header spar 53, which supports a controller header 54. The shape and dimensions of the controller header 54 is similarly related to the internal shape and dimensions of the controller channel 44, whereby the shape and dimensions of the controller header 54 allows movement within the controller channel 44 while also forming a substantially airtight seal between the outer edge of the controller header 54 and the internal wall of the controller channel 44.